

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

**DEFENDANTS ACTAVIS TOTOWA LLC,
ACTAVIS INC., AND ACTAVIS ELIZABETH LLC'S
RESPONSES TO PLAINTIFFS' SECOND SET OF REQUESTS FOR PRODUCTION**

Defendants Actavis Totowa LLC ("Actavis Totowa"), Actavis Inc. ("Actavis"), and Actavis Elizabeth LLC ("Actavis Elizabeth") ("Defendants") responds to Plaintiffs' Second Set of Requests for Production ("Requests") as follows:

RESERVATION OF RIGHTS

Defendants respond to Plaintiffs' Requests to the best of their present knowledge, information, and belief. These responses are subject to additional or different information that discovery or further investigation may disclose. Defendants do not waive or intend to waive, by reason of their responses, their rights to: (1) revise, amend, or supplement these responses; (2) object on any ground to the use of documents produced in these responses for any purpose, in whole or in part, in this or any other proceeding, action, or matter; (3) object on any grounds, at any time, to other discovery procedures or requests relating to the subject matter of the Requests; and (4) object on the grounds of admissibility to any documents produced in relation to the responses to these Requests.

GENERAL OBJECTIONS

Defendants make the following General Objections, which are in addition to, and incorporated within, each of the specific responses set forth below:

1. Defendants object to Plaintiffs' instructions and definitions to the extent they

attempt to enlarge the scope of permissible discovery under the Federal Rules of Civil Procedure, the Court's Pretrial Orders, and/or any other applicable rules.

2. Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way. As such, Defendants object to the Requests, and the definitions and the instructions, to the extent they imply that Actavis Inc. and Actavis Elizabeth were involved with, or are primary custodians possessing any responsive documents relating to, the manufacture of Digitek®. Furthermore, Defendants assert that the responses set forth herein shall not be considered a waiver of any objection or an acknowledgement by Actavis Inc. and Actavis Elizabeth of involvement with, or possession of responsive documents relating to, the manufacture of Digitek®.

3. Defendants object to Plaintiffs' use of the term "Digitek" to the extent that it pertains to any product not manufactured, distributed, or marketed under the trade name Digitek®. Defendants further object to the extent that Plaintiffs' use of the term "Digitek" includes ingredients or products not manufactured, marketed or distributed by a party to this lawsuit.

4. Defendants object to each Request to the extent it seeks any information or document relating to any drug other than Digitek®, the only product at issue in this litigation, which is not also reasonably related to the manufacture of Digitek® except to the extent disclosure of such information is required by the Court's Pre-trial Order #27 in this litigation ("PTO #27").

5. Defendants object to each Request to the extent it seeks information or documents protected from disclosure or production by the attorney-client privilege, the attorney work-product doctrine, joint defense or common interest privilege, accountant-client privilege, or by any other privilege or doctrine available under federal or state law, whether statutory, regulatory, constitutional, or common law. Defendants further object to each Request to the extent it seeks

the disclosure of information or documents protected by statutes, regulations, common law, and the Federal Rules of Civil Procedure that are either absolutely protected from production or which should be produced only pursuant to an appropriate protective order. Inadvertent disclosure of any such information shall not constitute a waiver of any privilege or any other ground for objecting to discovery with respect to such information, nor shall inadvertent disclosure waive the right of Defendants to object to the use of any such information in any proceeding.

6. Defendants object to each Request to the extent it seeks discovery or production of confidential, trade secret, and/or proprietary information.

7. Defendants object to each Request to the extent it calls for the discovery of information already in Plaintiffs' possession, custody, or control, information that is publicly available, or information that is otherwise equally available to Plaintiffs, on grounds that such requests for information are unreasonably cumulative and duplicative, and that such information is obtainable from a source that is more convenient, less burdensome, and less expensive.

8. Defendants object to each Request to the extent it seeks documents or information relating to the manufacturing and production process of Digitek® batches other than the batches that were the subject of the 2008 Digitek® recall on the grounds that such Request is overly broad, unduly burdensome, seeks information that is not relevant to the subject matter of this action, and is not reasonably calculated to lead to the discovery of admissible evidence.

9. Defendants object to the extent any Request seeks information concerning a period of time prior or subsequent to the time period that any Plaintiff allegedly ingested Digitek® on the grounds that such Request is overly broad, unduly burdensome, and seeks information that is not relevant to the subject matter of this action and is not reasonably calculated to lead to the discovery of admissible evidence.

10. Defendants object to each Request to the extent it is directed to any entity other

than Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC.

11. Defendants object to each Request to the extent it is vague, ambiguous, confusing, argumentative, overly broad, oppressive, and/or requires an unduly burdensome and unnecessarily expensive search for, and disclosure of, documents that are neither relevant to the claim or defense of any party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

12. Defendants object to each Request to the extent it is duplicative and cumulative.

13. Defendants object to each Request to the extent it calls for the disclosure of information or the production of documents not within Defendants' possession, custody, or control.

Defendants respond to these Requests without waiving the foregoing objections (which shall be deemed to apply to each and every Request), or any other objections set forth herein. In addition, pursuant to PTO #16, Defendants' production of documents in this matter is occurring on a rolling basis and is not yet complete. Some documents that are responsive to these Requests have already been produced and are identified in appropriate responses. Additional non-privileged responsive documents will be produced on a rolling basis pursuant to PTO #16 and these responses will be supplemented as necessary with each production.

RESPONSES TO REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 46:

All Documents from the Quality Systems / Quality Assurance Documentation Department relating to training in the manufacturing department for the past ten years.

RESPONSE TO REQUEST FOR PRODUCTION NO. 46:

Defendants object to this Request to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant events, and is thus overbroad and is not reasonably calculated to lead to the discovery of

REQUEST FOR PRODUCTION NO. 74:

All records of any internal investigations conducted in the last ten years involving or relating to Digitek® or any of its component parts or the raw materials used in the manufacture of Digitek®.

RESPONSE TO REQUEST FOR PRODUCTION NO. 74:

Defendants object to this Request to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to a request so overbroad in time and scope would be unduly burdensome for Defendants. This Request is also vague and confusing as written with respect to the undefined terms “internal investigations,” “component parts,” and raw materials.” Defendants further object to this Request to the extent it seeks documents protected by the attorney work-product doctrine, attorney-client privilege, and/or the joint defense privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Request but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Non-privileged responsive documents covering the period of January 1, 2003 through July 31, 2008, will be produced on a rolling basis pursuant to PTO #16.

REQUEST FOR PRODUCTION NO. 75:

All documents or records relating to any internal audits conducted by the compliance division or any quality department in the last ten years at any of the facilities used by Actavis Totowa LLC, including but not limited to the Little Falls Facility, the Taft Road Facility and the Riverview Facility.

RESPONSE TO REQUEST FOR PRODUCTION NO. 75:

Defendants object to this Request to the extent it is not limited to information concerning

Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to a request so overbroad in time and scope would be unduly burdensome for Defendants. Defendants will not provide any information and will not produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek® and except as required by PTO #27. The inclusion of the phrase “including but not limited to...” also makes this Request overbroad and fails to comply with Rule 34(b)(1)(A). This Request is also vague and confusing as written with respect to the undefined term “internal audits.” Defendants further object to this Request to the extent it seeks documents protected by the attorney work-product doctrine, attorney-client privilege, and/or the joint defense privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Request but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Non-privileged responsive documents relating to Digitek® covering the period of January 1, 2003 through July 31, 2008, if any, will be produced on a rolling basis pursuant to PTO #16.

REQUEST FOR PRODUCTION NO. 76:

All documents, communications or records relating to any inspections conducted by Actavis HF or the Actavis HF compliance inspection group in the last ten years of Actavis Totowa LLC or at any of the facilities used by Actavis Totowa LLC, including but not limited to the Little Falls facility, the Taft Road Facility and the Riverview Facility.

RESPONSE TO REQUEST FOR PRODUCTION NO. 76:

Defendants object to this Request to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or

relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to a request so overbroad in time and scope would be unduly burdensome for Defendants. Defendants will not provide any information and will not produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek® and except as required by PTO #27. The inclusion of the phrase “including but not limited to...” also makes this Request overbroad and fails to comply with Rule 34(b)(1)(A). This Request is also vague and confusing as written with respect to the undefined term “inspections.” Defendants further object to this Request to the extent it seeks documents protected by the attorney work-product doctrine, attorney-client privilege, and/or the joint defense privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Request but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Non-privileged responsive documents relating to Digitek® covering the period of January 1, 2003 through July 31, 2008, if any, will be produced on a rolling basis pursuant to PTO #16.

REQUEST FOR PRODUCTION NO. 77:

All procedures related to internal audits conducted by the compliance division or any quality department in the last ten years at any of the facilities used by Actavis Totowa LLC, including but not limited to the Little Falls Facility, the Taft Road Facility and the Riverview Facility.

RESPONSE TO REQUEST FOR PRODUCTION NO. 77:

Defendants object to this Request to the extent it is not limited to information concerning Digitek®, the only product at issue in this litigation, and is not limited to a relevant time frame or relevant persons and events, and is thus overbroad and is not reasonably calculated to lead to the

discovery of admissible evidence. Responding to a request so overbroad in time and scope would be unduly burdensome for Defendants. Defendants will not provide any information and will not produce any document relating to any drug other than Digitek® except where such information or document also reasonably relates to Digitek® or the manufacture of Digitek® and except as required by PTO #27. The inclusion of the phrase “including but not limited to...” also makes this Request overbroad and fails to comply with Rule 34(b)(1)(A). This Request is also vague and confusing as written with respect to the undefined term “internal audits.” Defendants further object to this Request to the extent it seeks documents protected by the attorney work-product doctrine, attorney-client privilege, and/or the joint defense privilege.

Actavis Inc. and Actavis Elizabeth were not involved in the manufacture, testing, distribution, or sale of Digitek® in any way, and as such they join in the objections to this Request but not the substantive response.

Subject to the foregoing objections, Defendants respond as follows: Non-privileged responsive documents covering the period of January 1, 2003 through July 31, 2008, if any, will be produced on a rolling basis pursuant to PTO #16.

REQUEST FOR PRODUCTION NO. 78:

All documents or records relating to any field alert reports issued by Actavis in the last ten years relating to Digitek® or any component parts or raw material used in the manufacture of Digitek®.

RESPONSE TO REQUEST FOR PRODUCTION NO. 78:

Defendants object to this Request to the extent it is not limited to a relevant time frame, and is thus overbroad and is not reasonably calculated to lead to the discovery of admissible evidence. Responding to a request so overbroad in time and scope would be unduly burdensome for Defendants. This Request is also vague and confusing as written with respect to the undefined terms “field alert reports,” “component parts,” and “raw materials.” Defendants